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OFFICE MEMORANDUM STANFORD UNIVERSITY

Date: June 19, 1963

To: Dr. Hubert Heffner, Department of Electrical Engineering

From: Carl Djerassi, Department of Chemistry

Subject: Patent Clause in NIH Research Grants

Earlier this week, I received a copy of the June 12, 1963 memorandum of Luther Terry, addressed to all NIH grantees, in which a copy of the regulations, published in the Federal Register, were enclosed. Critical comments were invited prior to August 1. As several members of your committee know, I feel very strongly about the patent policy, which in my opinion is unenforceable in its present form and which can be absolutely pernicious if enforced literally. Originally I had intended to send the following statement directly to Terry under my personal signature, but Dr. Axt suggested (and I concur completely with him) that I send this material in memorandum form to you for consideration by your committee. If the committee agrees with my views, it might be more effective if this statement (perhaps in somewhat rewritten form) were forwarded by it to the Surgeon General as an expression of opinion of a responsible university committee rather than of just one professor.

I would appreciate it if you would inform me in ample time whether the committee has decided to act on this subject or whether I should send this document (in letter form) to the Surgeon General under my own signature. I want to be sure that this material reaches him in one form or another before the stipulated deadline.

Statement

I would like to comment upon Paragraph 52.22 (Inventions or Discoveries) as discussed in further detail in Section 505 of the Grants Manual dated January 1, 1963.

The first sentence of Section 505, Paragraph A reads: "Department of Health, Education and Welfare regulations (45 CFR, Parts 6 and 8) provide as a condition that all inventions arising out of the activities assisted by Public Health Service grants and awards shall be promptly and fully reported to the Surgeon General" (my italics).

This report, according to Paragraph C, must take the following form:

"C. Formal Reports of Invention

In respect to inventions reported direct to the Surgeon General for determination under Department regulations, a formal report of invention is required in the nature of answers to 18 questions listed in the Outline for Invention Reports (Exhibit 2). The form and other specific instructions for submission of the report will be provided upon request.

Progress reports, which may include descriptions of inventions, may not substitute for formal reports of inventions."

At the outset, I would like to state that I am in complete agreement with the basic premise of the NIH patent policy -- namely, that inventions made under partial or complete NIH grant support should not be the subject of patents or patent applications benefitting the investigator or the institution. However, surely the corollary of this premise is not that all inventions should be patented by the Surgeon General or even that he should decide on the patentability of such inventions or discoveries. Rather,

such inventions or discoveries should be made available to the public -- the obvious and traditional route being the open scientific publication.

Why do I say that it is not proper or feasible for the Surgeon General to decide on the patentability of such discoveries? NIH form PHS 3945 (dated March 1962 and now included in every new grant application form) defines an invention in the very broadest terms. In fact, these terms are so broad that if the criterion of patentability is not left open to the individual investigator, a completely preposterous situation must arise. I shall cite one specific example. According to the present regulations, any invention or discovery (within the broad definition of PHS 3945) must be reported immediately to the Surgeon General. When this is done, the investigator receives by return mail an Outline for Invention Reports consisting of eighteen questions and included as Exhibit 2 in the Grants Manual. I personally have received such a questionnaire. If I answered it haphazardly, I could do so in half a day. If I answered it in a really proper manner, it would take several days. Only after the investigator has filled out this questionnaire and returned it to the NIH will the legal staff of the NIH decide whether this material is patentable, irrespective of whether the investigator wishes to take out a patent or even of whether he considers the material patentable.

I maintain that this procedure is not enforceable and would have preposterous consequences if any attempt were made to enforce it. Of the several thousand NIH grants, at least fifty percent are bound to contain some invention or discovery falling within the definition of NIH form PHS 3945. Many of the NIH grants will contain several such inventions or discoveries. Among the grants in chemistry or biochemistry, I would estimate that over eighty percent fall within this category. Any patent lawyer will confirm that the question of "patentability" is very difficult to answer and that the answer depends largely on one's attitude. If one is interested in securing a patent, a patent attorney can make a good case that a given subject is patentable, while the exact reverse can be accomplished if the attorney is trying to prove that a given subject is not patentable. One can estimate conservatively that of all chemical patents issued yearly by the U.S. Patent Office, fifty to seventy percent would be declared invalid if carried through the courts -- the reason being precisely the uncertainly which exists about what constitutes a real invention. I wonder whether the Surgeon General is aware of the fact that many patent applications are filed and patents granted in the chemical and pharmaceutical areas that do not include any experimental work at all -- all of the work on the invention or discovery being "paper work" and such patents being perfectly legal under our present system.

With this information as background, I performed the following experiment. I selected at random only one issue of a chemical journal, the April 1963 issue of the Journal of Organic Chemistry, and then picked out all articles which acknowledged NIH grant support. In the April issue there appeared seventeen such articles. Of these, I could select only three (pp. 900, 1075, and 1086) which I could say definitely did not contain patentable material. In three other instances (pp. 936, 945, and 1128), an excellent case could be made for patentability, including a statement of utility. Of the remaining eleven articles, in seven (pp. 923, 928, 942, 964, 1098, 1108, 1119) a good case could be made for patentability and in four (pp. 1004, 1015, 1037, and 1041) a weak case.

According to the present NIH rules, fourteen of these seventeen investigators should have filed an invention record and subsequently answered the eighteen questions of the Outline for Invention Reports. Reckoned conservatively in man-hours, this would take one to two months. But the real work would start only when the NIH legal staff received these documents and started wading through them. I would estimate that this experiment would have to be multiplied at least several hundredfold each year to cover all relevant grants and that the NIH would require a legal staff which would have to be much larger than the examiner staff of the U.S. Patent Office. It would also involve several hundred man-years of investigators' time to handle all the reports, answers, etc., and it should be remembered that

the most productive investigators or those with several collaborators may have many such invention reports each year at various stages of processing.

To complete the above small experiment from the April 1963 issue of the Journal of Organic Chemistry, I recommend that the Surgeon General put a member of his staff on the job of checking the seventeen grants to determine whether any invention statements have been filed. The chances are excellent that he will find none. The chances are poor that he will find two or three and the probability is infinitesimal that he will find even ten -- let alone the experimentally determined fourteen required statements.

Does this mean that all of these investigators are dishonest, that they are trying to utilize NIH funds without fulfilling regulations, that they are filing patents surreptitiously? The answer is that the present patent policy is unenforceable, has never been obeyed, and will not be obeyed -- either by the investigators (who would end up having little time for research if they followed literally the patent regulations) or by the NIH (who do not have even a fraction of the legal staff required to handle hundreds of such reports annually). I conclude, therefore, that the patent policy should be changed before some enormous uproar is raised by some uninformed individual, quite conceivably a congressman. I recommend that the patent policy be simplified and adapted to the de facto situation:

(a) No patents are to be filed by any NIH grantee unless he proceeds in the manner outlined in the present patent policy (Section 505, Paragraph A).

(b) But, if the NIH grantee does not intend to file a patent application, no specific report should be required of him, his annual progress report and the eventual publications representing sufficient evidence that he has complied with the spirit in which the grant was made.

It is conceivable that once every ten years some commercial company or other individual may secure a patent on an invention which that individual or company made independently but subsequent to an identical invention of an NIH grantee, the fact that the latter's publication did not appear soon enough (or that the material was covered only in an NIH report) having made it possible for the later inventor to secure such a patent. This is the only set of circumstances which the present policy could theoretically, but certainly not practically, prevent. If we really want to prevent such a hypothetical case, we -- the scientific community, the NIH, and the taxpayer -- will have to pay a ridiculous price to do so.

Carl Djerassi
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cc: Dr. R.G. Axt
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